

P₂ 21. (Amended) The instrument of claim 19, wherein the catalyst is at least one enzyme.

Please add new claim 29 to the application, as set forth below.

Sub 703
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29. (New) A sample solution treating instrument comprising a sample treating unit and a sample supply unit, wherein the sample treating unit contains an agent capable of converting the sample solution to a condition for analysis with a biosensor that electrochemically measures a specific component in a sample solution, the agent selected from the group consisting of a catalyst which is capable of converting an interfering substance in the sample solution to a harmless substance having no adverse effect on a measurement result of a specific component obtained by analysis with the biosensor, an adsorbent which is capable of adsorbing and removing an interfering substance from the sample solution, and a buffer agent which is capable of adjusting a pH of the sample solution to a pH range adequate for an activity of an enzyme in the biosensor.

REMARKS

Claims 19, 21, 24, 25 and 29 are pending in the application. In Paper No. 15, the Examiner has stated that, in view of the "constructive election," she considers claim 27 to be withdrawn. While the applicants do not agree that the restriction requirement is proper (see discussion provided, *infra*), claim 27 has been cancelled, without prejudice, in order to facilitate prosecution of this application.

Claims 20, 22, 23, and 26-28 have been cancelled, without prejudice. Claims 19 and 21 have been amended. No new matter is added by the amendments. Support for each of the amendments is found in the specification at least at pages 5 and 7-9. Pursuant to 37 C.F.R. § 1.121, a marked-up version of the amended claims, showing the changes made, is attached hereto.

New claim 29 has been added, a is a rewritten version of claim 11, as filed in the Preliminary Amendment with a Markush group added. Claim 29 does not incorporate new matter. Support for claim 29 is found at least at pages 7-9 of the specification.

For the Examiner's convenience, a complete set of pending claims is provided.

Restriction Requirement

At page 2 of Paper No. 15, the Examiner has asserted that newly submitted claim 27 is directed to an invention that is independent or distinct from the invention originally claimed because claim 27 requires a biosensor as part of the apparatus, which is a feature recited in the other claims. As ground for her assertion of a lack of independence or distinctness, the Examiner merely

states that "additional searching would be required for the feature." Additionally, the Examiner considered that the invention of claims 19-26 and 28 had been constructively elected because the applicants had previously received an action on the merits, and withdrew claim 27 from consideration. To facilitate the prosecution of this application, claim 27 has been cancelled, without prejudice. However, applicants respectfully submit that this restriction requirement is improper, and respectfully traverse it.

Claims 19-26 and 28 are directed to sample solution treating instruments that include a sample introducing part, a control means, and a sample releasing part. Claim 27 is directed to a sample solution treating instrument that includes a biosensor, a sample treating unit, and a sample supply unit.

There are two criteria that must be met in order to impose a requirement for restriction between patentably distinct inventions: (a) the invention must be independent or distinct as claimed; and (b) there must be a serious burden on the Examiner. M.P.E.P. 803. The Examiner must provide reasons and/or examples to support a restriction requirement. *Id.* First, to show that the technology of two claims are independent from one another, the Examiner must demonstrate that there is no disclosed relationship between the two technologies; they are unconnected in design, operation or effect. M.P.E.P. 803. Second, in order to satisfy the requirement of "serious burden", the Examiner must show, by appropriate explanation, either a separate classification, a separate status in the art, or a different field of search. M.P.E.P. 803.

In the present situation, the Examiner has made no attempt to show that the subject matters of claims 27 and of claims 19-26 and 28 are independent or distinct, nor has she shown that a serious burden that has been placed upon her. No analysis was provided to support the assertion of independence or distinctness and no showing of a separate classification, a separate status in the art, or a different field of search of each of claims 27 and of claims 19-26 and 28 was made.

Accordingly, as the Examiner has failed to meet both criteria for a proper requirement for restriction, applicants submit that the restriction requirement is not proper, and hereby make such position of record.

Rejection Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected claims 19-26 and 28 under 35 U.S.C. § 112, second paragraph, asserting that such claims are indefinite for use of various terms. In particular, the Examiner objects to the use of the term "adapted" in claims 19, 26, and 28 contending that the term renders the claim vague and indefinite because the applicant has not specified the way in which the instrument is adapted for use with the biosensor. While not necessarily agreeing with the Examiner, the applicants point out that claims 19, 26, and 28 have been amended or cancelled, such that the

pending claims no longer contain this language. Thus, this particular ground of rejection is no longer applicable.

Also at pages 2-3, the Examiner has rejected claims 20, 22-24, and 28, asserting use of the term "capable" makes the claims vague and indefinite as, according to the Examiner, it is unclear if the claim requires that the catalyst actually convert the interfering substance into a harmless substance or not. The applicants respectfully traverse this rejection, as applied to the pending claims.

Use of the term "capable" does not render the claims vague or indefinite. When read in conjunction with the specification, as is required, it is apparent that "capable of converting an interfering substance . . . to a harmless substance" in this context is a functional description of the catalyst. See, for example, the specification at page 8. The Examiner's ground for assertion of indefiniteness is, in this case, irrelevant, as the claim is an apparatus claim not a method claim, and there is no interfering substance recited in the claim which the catalyst could act to convert. There is merely a recitation that the structure of the catalyst is such that it is capable or structurally competent to convert the interfering substance when the product described by the claim is used.

Accordingly, for the reasons set forth above, it is respectfully requested that the Examiner reconsider and withdraw his 35 U.S.C. § 112, second paragraph, rejections.

Rejection Under 35 U.S.C. § 102

At pages 3-5 of Paper No. 15, the Examiner has rejected claims 19-26 and 28 under 35 U.S.C. § 102(b) or 102(e) as being anticipated by one or more of: (i) U.S. Patent No. 5,079,170 of Rosman, *et al.* ("Rosman"); (ii) U.S. Patent No. 4,270,923 of Kondo, *et al.* ("Kondo"); (iii) U.S. Patent No. 4,654,311 of Khanna, *et al.* ("Khanna"); (iv) U.S. Patent No. 5,492,834 of Liu, *et al.* ("Liu"); (v) U.S. Patent No. 5,945,345 of Blatt, *et al.* ("Blatt"); and (vi) U.S. Patent No. 5,571,419 of Obata, *et al.* ("Obata") (newly-cited). The applicants traverse each of these rejections for the reasons set forth below.

Rosman discloses a sample applicator for use in performing immunoassays to transfer liquid during the immunoassay preparation procedures. The applicator of Rosman contains a filter capable of removing particulate matter or of adding reagents to the liquid sample. The liquid sample is expelled from the Rosman application, then can be utilized in an immunoassay to detect or quantify a target protein. Particulate matter includes cellular debris, mucous, precipitated biological salts. The filter is capable of removing particulates having dimensions of about 0.5 μm . The Rosman filter may be made of polyesters, cellulose acetates, polyacrylonitriles, poly-(ethylene terephthalate).

Kondo discloses a method of removing interfering components and elements of turbidity present in a fluid for use in an immunologic pregnancy test by contacting the biological

fluid with a carboxylic acid- cation exchange resin fiber filter. Kondo teaches that a filter resin is packed into an open-ended tube through which the fluid is passed. The quantity of human chorionic gonadotropin in the filtered biological fluid is determined by a subsequent immunologic assay.

Khanna teaches a method of preparing a serum sample in order to enhance the accuracy of measurement of a digoxin in an assay. The Khanna method requires contacting a serum sample with a chromatographic column containing alkylated silica gel, washing the column, and diluting the digoxin from the chromatographic column. The purified digoxin is then assayed using labeling and/or immunologic means such as enzyme labels, fluorescence assays, or radioimmunoassays.

Liu discloses a means of preparing a body fluid composition for urine protein analysis. The process includes contacting the body fluid composition with a size exclusion gel having a molecular weight fractionation range or molecular weight exclusion range such that the size exclusion gel is capable of excluding or fractionating the urine proteins of interest from the remaining proteins present. The fractionated urine proteins are then quantified by electrophoretic methods, such as capillary zone electrophoresis.

Obata discloses a method of producing de-ionized water that greatly reduces the total organic carbon in the water. The process includes introducing raw water into various equipment including a cation exchange tower, an acidic softened water tank, a heat exchanger, a reaction vessel, a reverse osmosis membrane unit, a decarbonation tower, an anion exchange tower, and a pipe. *See*, Col. 5, lines 30-53.

In contrast, the present invention is a sample solution treating instrument. The instrument includes a sample introducing part, a control means for converting a sample solution to a condition for analysis by a biosensor that electrochemically measures a specific component in the sample solution, and a sample releasing part. The instrument is not physically coupled to the biosensor. Further, the control means comprises a converting agent which is a catalyst capable of converting an interfering substance in a sample solution to a harmless substance having no adverse effect on a measurement result of the specific component obtained by analysis with the biosensor, an adsorbent that is capable of adsorbing and removing an interfering substance from the sample solution or a buffer agent which is capable of adjusting a pH of the sample solution to a pH range adequate for an activity of an enzyme in the biosensor.

In order to anticipate an invention as claimed, the cited reference must teach each element of the invention. None of the Rosman, Kondo, Liu, and Obata discloses a sample solution treating instrument having a control means comprising an agent which is a catalyst, an adsorbent or a buffer agent as is recited in the claims. Each of these references teaches removal of any interfering

components by use of a filter through which the liquid or sample is passed, thereby separating the interfering substances by a physical separation.

Further, Khanna does not teach each element of the invention, as Khanna does not include a control means that comprises a catalyst or an adsorbent that is capable of adsorbing and removing the interfering substances. Khanna teaches use of a chromatographic column of alkylated silica gel, to which the analyte attaches, and from which it is subsequently removed in order to conduct analysis on purified analyte. In contrast, the adsorbent of the present invention adsorbs to and removes from the sample the interfering substances, not the desired analyte. Khanna, therefore, does not teach a control means that removes interfering substances.

Accordingly, for the reasons set forth above, none of the references cited by the Examiner teaches or suggests each element of the claimed invention. Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

In light of the foregoing, it is respectfully submitted that the pending claims are fully compliant with 35 U.S.C. § 112 and patentably distinguishable over all cited prior art. Consequently, reconsideration and allowance of all pending claims are respectfully requested at the earliest opportunity.

Respectfully submitted,

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Enclosures

Marked Up Version of Amended Claims

Complete Set of Pending Claims



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Marked-Up Version of Amended Claims

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19. (Amended) A sample solution treating instrument comprising:

(a) a sample introducing part;

(b) a control means for converting a sample solution to a condition for analysis by a biosensor that electrochemically measures a specific component in the sample solution, wherein the control means comprises an agent selected from the group consisting of a catalyst which is capable of converting an interfering substance in the sample solution to a harmless substance having no adverse effect on a measurement result of the specific component obtained by analysis with the biosensor, an adsorbent which is capable of adsorbing and removing an interfering substance from the sample solution, and a buffer agent which is capable of adjusting a pH of the sample solution to a pH range adequate for an activity of an enzyme in the biosensor; and

(c) a sample releasing part;

wherein the instrument [is adapted for use with a biosensor that electrochemically measures a specific component in a sample solution, but the instrument] is not physically coupled to the biosensor.

21. (Amended) The instrument of claim [20] 19, wherein the catalyst is at least one enzyme.